IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

CAROLE PARKINSON, Personal Representative of Carlie J. Odia (deceased) and her estate, 3:12-CV-02089-BR

OPINION AND ORDER

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

JEFFREY A. BOWERSOX

5285 Meadows Road Suite 320 Lake Oswego, OR 97035 (503) 452-5858

JOHN J. VECCHIONE

3863 Plaza Drive Fairfax, VA 22030 (703) 352-4800

Attorneys for Plaintiff

1 - OPINION AND ORDER

ANNE M. TALCOTT
RYAN P. BOYLE
JEFFREY D. HERN
Schwabe Williamson & Wyatt, PC
1600-1900 Pacwest Center
1211 S.W. Fifth Avenue
Portland, OR 97204
(503) 796-2991

KATHARINE R. LATIMER

DONALD W. FOWLER

GREGORY SCOTT CHERNACK

PHILIP M. BUSMAN

RANJIT S. DHINDSA

Hollingsworth LLP

1350 I Street, N.W.

Washington, DC 20005

(202) 898-5850

Attorneys for Defendant

BROWN, Judge.

This matter comes before the Court on Defendant Novartis

Pharmaceuticals Corporation's Motion (#45) to Exclude the

Testimony of Plaintiff's Expert Dr. Eric Sung and Defendant's

Motion (#51) for Summary Judgment. For the reasons that follow,

the Court GRANTS Defendant's Motion for Summary Judgment, DENIES

as moot Defendant's Motion to Exclude, DENIES as moot all other

pending Motions, and DISMISSES this matter with prejudice.

FACTUAL BACKGROUND

On January 13, 2003, Plaintiff Carlie Odia¹ was diagnosed with stage IIIB breast cancer and began undergoing chemotherapy.

On June 19, 2003, Plaintiff refused to receive any further chemotherapy.

On May 23, 2005, Plaintiff underwent radiation therapy of her pelvis to treat "intractable pain" caused by her "extensively metastic" breast cancer. Joint Statement of Agreed Facts, Ex. 6 at 1.

On May 25, 2005, Plaintiff underwent surgery to address "impending fractures in both femurs." Def.'s Mem. in Support of Summ. J., Ex. 9 at 1. Jeffrey Lyman, M.D., treating surgeon, noted Plaintiff had "metastatic disease with more than 50 percent cortical involvement of the left side and significant pain and lucencies consistent with metastatic disease on the right as well." Id.

On May 27, 2005, Mark Seligman, M.D., treating physician, noted the following with respect to Plaintiff:

The patient is known to have breast cancer. The presentation with a large axillary mass certainly sounds ominous. She has metastatic disease at this time documented in her bones, and a recent CT scan certainly suggests pulmonary metastases as well. Treatment of stage 4 breast cancer is palliative, but there are several treatment

¹ Odia is deceased. This action was brought on her behalf by her personal representative Carole Parkinson. The Court, however, will refer to Odia as Plaintiff for clarity.

^{3 -} OPINION AND ORDER

modalities that can produce good palliation and extend longevity. . . . I am going to treat her with a bisphosphonate. Bisphosphonates have an important role in preventing adverse bony events in patients with bony metastases. They decrease bone pain as well. They are also useful as anti hypercalcemic agents. I notice that the patient's chemistry profile showed a calcium of 10.5 preoperatively. She is now somewhat immobilized, and has extensive metastases, and, she is therefore certainly at risk for hypercalcemia.

Def.'s Mem. in Support of Summ. J., Ex. 10 at 3-4.

In June 2005 Dr. Seligman started Plaintiff on monthly infusions of Aredia, a bisphosphonate.

Dr. Seligman testified at deposition that when he prescribed Aredia for Plaintiff in June 2005, he was "aware of bisphosphonates as [a] potential risk factor for [Osteonecrosis of the Jaw] ONJ." Def.'s Mem. in Support of Summ. J., Ex. 13 at 116. Nevertheless, Dr. Seligman prescribed Aredia for the reasons noted in his May 27, 2005, chart note and because

[i]n oncology [bisphosphonates are] used because they improve the quality of patients' lives by increasing the strength of the bone, preventing bad bone events, by which we mean fractures and collapses of bones; improving pain. They also lower the calcium for patients who need that. And they do so - and these benefits are somewhat -- between 30 and 50 percent of bad bone events are prevented by the use of these medications.

Def.'s Mem. in Support of Summ. J., Ex. 13 at 36. Dr. Seligman believes the benefits of bisphosphonates outweigh the risk of ONJ and continues to prescribe Aredia and Zometa to patients today.

Id. at 132.

By June 27, 2005, Plaintiff was using a walker and a wheelchair due to her metastic cancer "with bony metastases."

Def.'s Mem. in Support of Summ. J., Ex. 8 at 1.

By August 2005 Plaintiff was "immobile" and "unable to engage in activities of daily living of any kind" due to skeletal complications resulting from her cancer metastasizing to her bones. Def.'s Mem. in Support of Summ. J., Ex. 7 at 51-52.

On July 19, 2006, Plaintiff underwent a total right hip arthroplasty to address the diagnosis of "posttramatic osteoarthritis secondary to tumor necrosis and osteonecrosis" in her right hip. Joint Statement of Agreed Facts, Ex. 8 at 1.

On September 7, 2006, Dr. Seligman changed Plaintiff's bisphosphonate from Aredia to Zometa because Zometa has a significantly shorter infusion time.

On December 6, 2006, Plaintiff went to the Multnomah County Health Department to obtain dental care for the first time in five years. Plaintiff reported on the Multnomah County Health Department's Dental Health History form that she had an infected upper left molar and had lost a crown. Joint Statement Agreed Facts, Ex. 11 at 1. Plaintiff also reported she was not undergoing any medical or health treatment, she did not have any medical or health provider "at the moment," and she was not on any medication. Id. at 2. In the portion of the Dental Health History form in which Plaintiff was asked to circle any

conditions she "ha[s] or . . . ha[s] ever had, " Plaintiff did not circle cancer or radiation treatment and instead circled "none of the above." \emph{Id} .

Plaintiff was examined and evaluated by Michelle Keys,
D.M.D., who noted swelling at Plaintiff's tooth #14, which was
missing a crown and had severe decay. Def.'s Mem. in Support of
Summ. J., Ex. 31 at 1. Dr. Keys concluded the tooth was
"nonrestorable." Id. Dr. Keys testified at deposition that
there were not any dental procedures she believed "would work to
save that tooth" nor any alternatives to extracting the tooth.
Dr. Keys, therefore, extracted the tooth in an uncomplicated
procedure on December 6, 2006. Def.'s Mem. in Support of Summ.
J., Ex. 30 at 66. Dr. Keys testified at deposition that there is
not anything in Plaintiff's records that indicates to Dr. Keys
that she should have been aware in December 2006 that Plaintiff
had cancer or that she was under the care of another physician.
Id. at 34.

In December 2006 Plaintiff was also scheduled to undergo a root canal on the adjoining tooth (#13). After cancelling twice, Plaintiff returned to the Multnomah County Health Department on September 21, 2007, for an examination and evaluation of tooth #13.

On September 21, 2007, Plaintiff was examined by Athena Bettger, D.M.D., and diagnosed with a possible fracture of tooth

#13 and irreversible pulpitis. Def.'s Mem. in Support of Summ.

J., Ex. 32 at 1. Dr. Bettger recommended extracting tooth #13

because that tooth had a "poor/hopeless prognosis." Id. At

deposition Dr. Bettger explained Plaintiff's "tooth [#13] was

mobile had a poor longevity because of the poor crown-to-root

ratio, and there was a possible fracture. The tooth [was]

non-restorable." Def.'s Mem. in Support of Summ. J., Ex. 26 at

61. Dr. Bettger also did not know Plaintiff had cancer when she

treated her in September 2007. The fact that a patient has

cancer is something Dr. Bettger would have noted in the patient's

chart, but Plaintiff's chart did not contain any such note.

On September 28, 2007, Plaintiff called the Multnomah County
Health Department to report that she was still swollen and in
pain from her September 21, 2007, extraction of tooth #13.

On October 1, 2007, Plaintiff returned to the Multnomah

County Health Department and was again seen by Dr. Bettger. At

that appointment Plaintiff advised Dr. Bettger for the first time

that she had breast cancer and was taking Zometa. Dr. Bettger's

treatment notes reflect she discussed with Plaintiff that her

problem might be "bisphosphonate related osteonecrosis" and that

Plaintiff "became agitated stating 'it's just dry socket.'"

Def.'s Mem. in Support of Summ. J., Ex. 33 at 1.

At some point Dr. Myall saw Plaintiff about her jaw issues and noted Plaintiff might be suffering from ONJ.

On January 30, 2008, Plaintiff was seen by Brian Woo, D.M.D., oral surgeon, who concluded Plaintiff had bisphosphonate-related ONJ "associated with extraction sites of teeth #13 and #14." Def.'s Mem. in Support of Summ. J., Ex. 35 at 2. Dr. Woo started Plaintiff "on Pendex mouth rinses and local wound care along with chronic oral antibiotics." *Id*.

On January 30, 2008, Dr. Myall saw Plaintiff for evaluation of her ONJ. Plaintiff advised Dr. Myall that "her symptoms have improved and there have been no signs of infection." Def.'s Mem. in Support of Summ. J., Ex. 34 at 1. Dr. Myall noted Plaintiff's ONJ "has stayed quiescent and may have improved slightly. There is no need for intervention at this time." *Id.* at 2.

Plaintiff died on October 9, 2008.

PROCEDURAL BACKGROUND

On March 20, 2008, Plaintiff brought an action against

Defendant in the United States District Court for the District of

Columbia seeking compensatory and punitive damages on the ground

that Aredia and Zometa caused her to develop ONJ. Plaintiff

brought claims for (1) strict liability, (2) negligent

manufacture, (3) negligent failure to warn, (4) breach of express

warranty, and (5) breach of implied warranty of merchantability.

At some point the Judicial Panel on Multidistrict Litigation (MDL) transferred Plaintiff's action to the United States

District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1407. Following discovery and briefing of dispositive motions in the MDL court, the MDL panel remanded the matter to the United States District Court for the District of Columbia.

In November 2012 the United States District Court for the District of Columbia transferred the matter to this Court.

On March 11, 2013, Plaintiff filed an Amended Complaint against Defendant in which she brings claims for (1) strict liability, (2) negligent manufacture, (3) negligent failure to warn, (4) breach of express warranty, and (5) breach of implied warranty of merchantability. Plaintiff continues to seek compensatory and punitive damages.

On October 4, 2013, Defendant filed a Motion for Summary

Judgment. On that same day Defendant also filed, among other

motions, a Motion to Exclude the Testimony of Plaintiff's Expert

Dr. Eric Sung.

On January 23, 2014, the Court heard oral argument on Defendant's Motion for Summary Judgment and Defendant's Motion to Exclude the Testimony of Dr. Sung. At the hearing the Court directed the parties to file no later than January 31, 2014,

² Although Plaintiff does not specify in her Amended Complaint whether her claims are brought under common law or Oregon statute, Plaintiff advised the Court at oral argument that her claims are brought pursuant to Oregon Revised Statute § 30.920.

^{9 -} OPINION AND ORDER

supplemental briefing to set out concisely the facts underlying their legal arguments.

The Court took this matter under advisement on January 31, 2014.

DEFENDANT'S MOTION (#51) FOR SUMMARY JUDGMENT

I. Standards.

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Washington Mut. Ins. v. United States, 636 F.3d 1207, 1216 (9th Cir. 2011). See also Fed. R. Civ. P. 56(a). The moving party must show the absence of a dispute as to a material fact. Rivera v. Philip Morris, Inc., 395 F.3d 1142, 1146 (9th Cir. 2005). In response to a properly supported motion for summary judgment, the nonmoving party must go beyond the pleadings and show there is a genuine dispute as to a material fact for trial. Id. "This burden is not a light one.

. . . The non-moving party must do more than show there is some 'metaphysical doubt' as to the material facts at issue." In re Oracle Corp. Sec. Litig., 627 F.3d 376, 387 (9th Cir. 2010) (citation omitted).

A dispute as to a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Villiarimo v. Aloha Island Air, Inc., 281 F.3d

1054, 1061 (9th Cir. 2002) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). The court must draw all reasonable inferences in favor of the nonmoving party. Sluimer v. Verity, Inc., 606 F.3d 584, 587 (9th Cir. 2010). "Summary judgment cannot be granted where contrary inferences may be drawn from the evidence as to material issues." Easter v. Am. W. Fin., 381 F.3d 948, 957 (9^{th} Cir. 2004)(citation omitted). A "mere disagreement or bald assertion" that a genuine dispute as to a material fact exists "will not preclude the grant of summary judgment." Deering v. Lassen Cmty. Coll. Dist., No. 2:07-CV-1521-JAM-DAD, 2011 WL 202797, at *2 (E.D. Cal., Jan. 20, 2011) (citing Harper v. Wallingford, 877 F.2d 728, 731 (9th Cir. 1989)). When the nonmoving party's claims are factually implausible, that party must "come forward with more persuasive evidence than otherwise would be necessary." LVRC Holdings LLC v. Brekka, 581 F.3d 1127, 1137 (9th Cir. 2009)(citation omitted).

The substantive law governing a claim or a defense determines whether a fact is material. *Miller v. Glenn Miller Prod.*, *Inc.*, 454 F.3d 975, 987 (9th Cir. 2006). If the resolution of a factual dispute would not affect the outcome of the claim, the court may grant summary judgment. *Id*.

II. Oregon's General Products-Liability Statute.

Oregon Revised Statute § 30.920(1) provides:

(1) One who sells . . . any product in a

11 - OPINION AND ORDER

defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm . . . caused by that condition, if:

- (a) The seller or lessor is engaged in the business of selling . . . such a product; and
- (b) The product is expected to and does reach the user or consumer without substantial change in the condition in which it is sold or leased.

Oregon Revised Statute § 30.900 provides:

As used in ORS 30.900 to 30.920, "product liability civil action" means a civil action brought against a manufacturer . . . of a product for damages for personal injury . . . arising out of:

- (1) Any design, inspection, testing, manufacturing or other defect in a product;
- (2) Any failure to warn regarding a product; or
- (3) Any failure to properly instruct in the use of a product.

Oregon courts have held § 30.900, "embraces all theories a plaintiff can claim in an action based on a product defect,"
Kambury v. DaimlerChrysler Corp., 185 Or. App. 635, 639 (2003), including, but not limited to, claims based on theories of negligence and strict liability. Simonsen v. Ford Motor Co., 196 Or. App. 460, 466 (2005).

Accordingly, all of Plaintiff's claims must be brought pursuant to Oregon's product-liability statutes §§ 30.900-30.920.

III. Adequacy of the Warnings for Aredia and Zometa.

"[T]he manufacturer of . . . drugs bears the . . . duty of 12 - OPINION AND ORDER

making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know." McEwen v. Ortho Pharm. Corp., 270 Or. 375, 386 (1975). See also Warner v. Stryker Corp., Civ. No. 08-6368-AA, 2011 WL 5999339, at *2 (D. Or. Nov. 28, 2011)(same); Kildow v. Breg, Inc., 796 F. Supp. 2d 1295, 1299 (D. Or. 2011) (same).

Defendant contends it is entitled to summary judgment because the warnings provided by Defendant as to Aredia and Zometa were adequate as a matter of law at the time that Plaintiff took those products.

Plaintiff, however, contends the adequacy of a warning is usually a question of fact for the jury. See, e.g., Reiger v.

Toby Enterprise, 45 Or. App. 679, 684 (1980). See also Benjamin v. Wal-Mart Stores, Inc., 185 Or. App. 444, 455 (2002)(same).

Plaintiff also points out that the MDL judge found there was a genuine dispute of material fact as to whether the warnings provided by Defendant as to Aredia and Zometa were adequate at the time that Plaintiff was taking those medications. Plaintiff relies on an order by the MDL court in which it summarized various proceedings before that court and stated in pertinent part: "The Court found that there are genuine issues of material fact as to whether Novartis' warnings concerning Aredia and Zometa were adequate. (Docket Nos. 2766 and 2767.)" In re

Aredia and Zometa Prods. Liab. Litig., 2011 WL 2182824, at *5 (M.D. Tenn. June 3, 2011).

In Deutsch v. Novartis Pharmaceuticals Corporation the court noted:

It is well-established that "[o]rders issued by a federal transferee court remain binding if the case is sent back to the transferor court." In re Zyprexa Prods. Liab, Litiq., 467 F. Supp. 2d 256, 273 (E.D.N.Y. 2006)(citing Manual for Complex Litigation § 20.133 (4th ed. 2004)). As the Supreme Court has stated, the law of the case doctrine "posits that when a court decides a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." Arizona v. California, 460 U.S. 605, 618 (1983); see also Aramony v. United Way of Am., 254 F.3d 403, 410 (2d Cir. 2001). This doctrine is discretionary and a court "may depart from the law of the case for 'cogent' or 'compelling' reasons including an intervening change in law, availability of new evidence, or 'the need to correct a clear error or prevent manifest injustice.'" Johnson v. Holder, 564 F.3d 95, 99-100 (2d Cir. 2009) (quoting United States v. Quintieri, 306 F.3d 1217, 1230 (2d Cir. 2002)).

* * *

Furthermore, any reversal of the MDL court rulings would undermine the purpose of the Multi District Litigation Act, which authorizes the coordinated and consolidated pretrial proceedings of civil actions involving one or more common issues of fact "for the convenience of parties and witnesses and [to] promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). . . . prevent inconsistent pretrial rulings on the admissibility of expert testimony, it is only in "exceptional cases, [that] the federal or state court to which an MDL case is transferred or remanded may revisit a transferee court's decision." Zyprexa, 467 F. Supp. 2d at 274 (E.D.N.Y. 2006)(citing Manual for Complex Litigation § 20.133 ("Although the transferor

judge has the power to vacate or modify rulings made by the transferee judge, subject to comity and 'law of the case' considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings.")). Reversing or otherwise undermining the decisions by the MDL court could lead to the type of inconsistent pretrial rulings that Congress sought to avoid, and therefore frustrate the very purpose of consolidation.

768 F. Supp. 2d 420, 428-29 (E.D.N.Y. 2011).

Defendant did not address the ruling of the MDL panel in its Reply or at oral argument.

This Court agrees with the Deutsch court and finds reversing or otherwise undermining the decision by the MDL court that disputes of material fact exist as to the adequacy of Defendant's warnings "could lead to the type of inconsistent pretrial rulings that Congress sought to avoid, and therefore frustrate the . . . purpose of consolidation." 768 F. Supp. 2d at 429. The Court, therefore, declines to revisit the adequacy of Defendant's warnings and adheres to the conclusion of the MDL that genuine disputes of material fact exist as to whether Novartis's warnings concerning Aredia and Zometa were adequate at the time that Plaintiff was taking those medications.

IV. Plaintiff has not established there is a genuine dispute of material fact as to whether any alleged deficiency in the Aredia and Zometa warnings was the proximate cause of Plaintiff's injury.

"'[T]he plaintiff in a strict liability case is required to establish that [the alleged inadequate warning] proximately

15 - OPINION AND ORDER

caused [her] injuries or damages.'" Crosswhite v. Jumpking,

Inc., 411 F. Supp. 2d 1228, 1235 (D. Or. 2006)(quoting Gilmour v.

Norris Paint & Varnish Co., Inc., 52 Or. App. 179, 184 (1981).

"Oregon courts have held that an inadequate warning 'must be a substantial cause of the person's injuries.'" Id. (quoting

Benjamin v. Wal-Mart Stores, Inc., 185 Or. App. 444, 458 (2002)).

Plaintiff contends Defendant "must overcome the presumption that an adequate warning would have been read and prevented the harm" to succeed on summary judgment. To support its contention, Plaintiff relies on an unpublished Ninth Circuit case in which the court aplied Alaska law: Ellis v. Coleman Co., Inc., Nos. 99-35341, 99-35370, 2000 WL 1131893 (9th Cir. Aug. 9, 2000). Pursuant to Ninth Circuit Rule 36-3(c), however, "[u]npublished dispositions and orders of this Court issued before January 1, 2007, may not be cited to the courts of this circuit" absent circumstances not present here. In any event, Plaintiff does not cite and the Court could not find a case in which a court applied any such presumption under Oregon law. The Court, therefore, concludes there is not a presumption under Oregon law that an adequate warning "would have been read and prevented the harm." As noted, under Oregon law the burden is on the plaintiff to "establish that [the alleged inadequate warning] proximately caused [her] injuries or damages." Gilmour, 52 Or. App. at 184. Thus, to defeat Defendant's Motion for Summary Judgment Plaintiff

must show there is evidence creating at least a genuine dispute of material fact as to whether the allegedly inadequate warning was a substantial cause of her injuries. Put another way, Defendant asserts it is entitled to summary judgment because Plaintiff cannot establish the alleged deficiency in the Aredia/Zometa warning was a substantial cause of her injury; i.e., that a different warning would have prevented her injury. In particular, Defendant notes when Dr. Seligman prescribed Aredia and Zometa to Plaintiff in 2005 and 2006, he was aware that bisphosphonates were a "potential risk factor for ONJ." Def.'s Mem. in Support, Ex. 13 at 116. Although Dr. Seligman knew of thousands of scientific articles in 2005 and 2006 that set out and described the various risks associated with Aredia and Zometa (including ONJ), the evidence is undisputed that Dr. Seligman, nevertheless, chose to prescribe Aredia and Zometa for Plaintiff because the benefits to Plaintiff ("increasing the strength of the bone, preventing bad bone events, by which we mean fractures and collapses of bones; improving pain"; and lowering calcium levels) outweighed the risk of ONJ.

These undisputed facts are similar to those in Luttrell v. Novartis Pharmaceuticals Corporation in which the Ninth Circuit recently concluded: "[E]ven assuming that Novartis' warnings were inadequate, we conclude that the district court properly granted summary judgment to Novartis because Luttrell cannot

prove proximate cause." No. 12-35893, 2014 WL 644880, at *1 (9th Cir. Feb. 20, 2014). The court noted "[t]he record makes clear . . . the doctor understood the connection between bisphosphonates and the risk of osteonecrosis of the jaw, and that in his medical opinion the benefits of the treatment for the patient outweighed those risks." *Id*. The Court notes the record here reflects Dr. Seligman continues to prescribe Aredia and Zometa today despite the risks of ONJ because the benefits "greatly outweigh" the risks. Def.'s Mem. in Support, Ex. 13 at 132.

Nevertheless, Plaintiff contends she would not have consented to be treated with Aredia and Zometa if she had known of the possible risk of ONJ, and to support that contention, Plaintiff relies on the Declaration of Carole Parkinson. In her Declaration Parkinson states the deceased (her daughter) would not have taken Aredia or Zometa if she had been warned about the possibility of ONJ. The Court notes Parkinson does not testify her daughter advised Parkinson that she would not have taken Aredia or Zometa. Instead Parkinson points to two typewritten paragraphs that she states she found in her daughter's papers after her death. Even if the typewritten paragraphs were admissible for the purposes of this Motion, however, the statements do not support the conclusions in Carole Parkinson's Declaration. Although the deceased states in both statements

that she was not warned about the risk of ONJ related to Aredia or Zometa,³ the deceased does not state at any point in either document that she would not have taken Aredia or Zometa if she had known of the ONJ risk. Moreover, Parkinson acknowledged at deposition that during her daughter's treatment, Parkinson was not "aware of her [daughter] deciding not to take any drugs because of the potential risks or side effects." Def.'s Mem. in Support of Summ. J., Ex. 39 at 21. Accordingly, whether the deceased would have refused to take Aredia or Zometa is speculative and insufficient to create a jury question as to causation.

Moreover, the Ninth Circuit has made clear that the relevant inquiry is not whether *Plaintiff* would have taken Zometa, but whether *Dr. Seligman* would have prescribed Aredia and Zometa if he had received a different warning related to the possibility of ONJ. See Luttrell, 2014 WL 644880, at *1 ("When a plaintiff brings an insufficient warning claim against a drug company, the learned intermediary doctrine requires a showing that the prescribing physician, not the patient, would have taken a different course of action if better warnings had been issued"

³ Needless to say, Defendant disputes this point. Dr. Seligman testified at deposition that he would have talked to Plaintiff about the risks associated with Aredia before he prescribed it and, as noted, that he was intimately familiar with the risks due to "thousands" of articles and pieces of information he had encountered related to the use of Aredia in 2005.

(quotation omitted)). As noted, Dr. Seligman was well aware of the risk of ONJ when he prescribed Aredia and Zometa to Plaintiff, and he continues to prescribe Aredia and Zometa today because it remains the standard of care and its benefits outweigh the risks.

In addition, numerous courts have held an allegedly deficient warning from a prescription product's seller cannot be the proximate cause of the plaintiff's injuries when a prescribing physician would still take the same course of action if he or she had been differently or "more adequately" warned. See, e.g., Mattson v. Bristol-Myers Squibb Co., No. 07-908, 2013 WL 1758647, at *5 (D.N.J. Apr. 24, 2013) (under California law the pharmaceutical defendant was entitled to summary judgment when the plaintiff failed to present any evidence that a different warning would have affected the prescribing physician's decision to prescribe the drug); In re Trasylol Prods. Liab. Litig., No. 08-MD-01928, 2013 WL 1080552, at *12 (S.D. Fla. Mar. 14, 2013)(same applying Oklahoma law); Solomon v. Bristol-Myers Squibb Co., 916 F. Supp. 2d 556, 569 ((D.N.J. 2013)(same applying Texas law); McElroy v. Eli Lilly & Co., 495 F. App'x 166, 168 (2d Cir. 2012)(same applying Nebraska law); Sauls v. Wyeth Pharm., Inc., 846 F. Supp. 2d 499, 503-504 (D.S.C. 2012) (same applying South Carolina law); Miller v. Alza Corp., 759 F. Supp. 2d 929, 936-37 (S.D. Ohio 2010)(same applying Ohio law);

Dietz v. SmithKline Beecham Corp., No. 4:07-CV- 0077-RLV, 2008 WL 5329295, at *4 (N.D. Ga. Dec. 9, 2008)(same applying Georgia law).

Plaintiff, however, maintains it is sufficient that

Drs. Keys and Bettger "changed their practice with regards to

going over treatment options with patients" since the time they

treated Plaintiff. The Court notes Dr. Keys could not recall

whether she was familiar with Aredia, Zometa, or bisphosphonates

in general at the time that she treated Plaintiff in December

2006:

My first knowledge of the possible relationship between ONJ and dental extractions, I don't recall the time line. But at first it appeared that there was still some questions whether or not there was a relationship. At that time, I may not have had been quite as insistent on specifics in telling the patient there absolutely is a connection. Now more insistent with the patient that they understand that -- that there may be a connection between the two, and that now I'm that they need to understand the possibilities before they make the decision to take a tooth out.

Plf.'s Resp., Ex. 21 at 49. Dr. Bettger's practice "with respect to treating patients who were taking bisphophonates" at the time that she treated Plaintiff in 2007 was as follows:

I would request a mediconsult with her primary care doctor and her oncologist. . . . I would like to know what type of medications and how stable her health is prior to surgery.

* * *

I would say, I would like to get a medical consult with your primary care provider and the doctor who

is helping you with your oncology treatment. There are some cases of delayed healing relative to dental extractions.

Def.'s Mem. in Support of Summ. J., Ex. 26 at 40, 41. Although Dr. Bettger had Plaintiff sign a "particular consent form" in September 2007, Dr. Bettger's office evidently added at some later time "an additional consent form . . . for extractions." ⁴ Id. at 61.

Plaintiff does not cite any authority to support her assertion that the fact that Dr. Keys is now "more insistent with the patient that they understand that . . . there may be a connection between the two" or that Dr. Bettger currently offers an additional consent form that may or may not address bisphosphonate use establishes a jury question as to whether an allegedly inadequate warning was a substantial cause of Plaintiff's injury. As noted, there is not any evidence in the record that there was any alternative treatment to removal of Plaintiff's #13 tooth. Dr. Bettger's treatment notes reflect Plaintiff's tooth #13 had a "poor/hopeless prognosis," and Dr. Bettger explained Plaintiff's "tooth [#13] was mobile had a poor longevity because of the poor crown-to-root ratio, and there was a possible fracture. The tooth [was] non-restorable."

⁴ The new form is not in the record nor does the record reflect whether Dr. Bettger asks specifically in the new form about the use of bisphosphonates or provides a specific warning related to their use.

^{22 -} OPINION AND ORDER

Def.'s Mem. in Support of Summ. J., Ex. 26 at 61. Dr. Bettger concluded tooth (#13) had to be extracted. Similarly, Dr. Keys testified at deposition that there were not any dental procedures that she believed "would work to save that tooth" (#14), and there was not any alternative to extracting the #14 tooth.

Def.'s Mem. in Support of Summ. J., Ex. 30 at 66.

In any event and most importantly, the record reflects

Plaintiff failed to advise any of her dental-treatment providers

until after both of her teeth had been extracted that she (1) had

cancer, (2) was taking Aredia or Zometa, or (3) was under the

care of any other doctor for any other condition. Plaintiff also

did not advise Dr. Seligman that she had undergone an extraction

of tooth #14 or that she had #13 removed until after she suffered

side effects. Accordingly, no rational jury could conclude that

more or different warnings from Defendant could have prevented

Dr. Bettger from extracting Plaintiff's tooth #13 because

Plaintiff failed in the first instance to inform any medical

professional at the Multnomah County Health Department's Dental

Clinic that she had cancer and was taking Aredia and/or Zometa.

The Oregon Supreme Court held as early as 1975 that the failure to inform treating physicians of certain symptoms severs the causal connection between any alleged negligence and the injury. See Vaughn v. G. D. Searle & Co., 272 Or. 367 (1975). In Vaughn the plaintiff sued the manufacturer of the drug Ovulen

for injuries suffered as a result of a stroke that the plaintiff alleged was caused by taking Ovulen. The plaintiff asserted the defendant was negligent when it failed to provide adequate warnings to the medical profession regarding "the dangerous propensities of its product." Id. at 368. The court concluded "there was no evidence that any failure to warn plaintiff's physicians was a substantial factor in producing plaintiff's injuries and that defendant's motion for a directed verdict should have been granted." Id. at 375. The court noted:

[P]laintiff has offered no evidence, either direct or indirect, that she ever advised her treating physicians of symptoms which would have alerted them to the possibility of a stroke. Without such knowledge there was no way the physician could have related any warning (that there is a cause-and-effect relationship between the ingestion of the drug and a stroke) to plaintiff's particular case. Thus, there was no evidence that even a properly warned physician would have treated plaintiff differently or removed her from defendant's oral contraceptive prior to her stroke.

Id. at 373. Here Plaintiff has failed to establish a jury question as to whether any alleged failure by Defendant to warn Plaintiff's physicians was a substantial factor in producing Plaintiff's injuries because Plaintiff failed to advise Dr. Seligman that she was undergoing dental treatment and concurrently failed to advise Drs. Keys and Bettger that she had cancer and was being treated with Aredia and Zometa.

On this record, therefore, the Court concludes Plaintiff has

not established there is a genuine dispute of material fact as to whether Defendant's allegedly inadequate warnings for Aredia and Zometa were the legal cause of Plaintiff's injury regardless whether causation is measured as "proximate" or "a substantial factor." Accordingly, the Court grants Defendant's Motion for Summary Judgment as to Plaintiff's claims for (1) strict liability, (2) negligent manufacture, and (3) negligent failure to warn under Oregon Revised Statute § 30.920.

V. Plaintiff's Claim for Breach of Warranty.

Plaintiff also brings claims for breach of express and implied warranties. Defendant moves for summary judgment against those claims and asserts the Court must dismiss them because Plaintiff failed to give the notice required for those claims under Oregon law.

Oregon Revised Statute § 72.6070(3) provides when a tender of goods has been accepted, "[t]he buyer must within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy."

This district has interpreted the notice requirement of § 72.6070(3) to apply in warranty actions "for personal injuries resulting from the purchase of a consumer product," including an action against a contraceptive drug maker. Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1160 (D. Or. 1989). In Allen the court granted the defendant's motion for summary judgment on the

plaintiff's warranty claims:

The court has not located any Oregon decision holding that notice is no longer required in a warranty action for personal injuries resulting from the purchase of a consumer product. On the contrary, in Redfield, supra, an action against a contraceptive drug manufacturer, the Oregon Supreme Court stated that O.R.S. 72.6070 "indicates that notice is an essential element of plaintiff's case" for breach of warranty. at 284, 512 P.2d 776. In the absence of any authority for abolishing the notice requirement, and in the absence of any evidence that Allen gave notice of her express or implied warranty claims, this court must rule that Allen has not established an essential element of her warranty claims.

Id.

Plaintiff argues "Defendant relies on the Oregon Uniform Sales Act, Or. Rev. Stat. § 75.490. Under this statute, a buyer must give notice to the seller before it sues for breach of contract. However, under this statute notice would not be required if it would be futile." The Court notes Plaintiff does not cite any case to support her assertion as to futility and, indeed, does not provide any legal analysis on that point.

Moreover, Defendant relies on Oregon's current Uniform Commercial Code § 72.6070 (which does not contain any provision excusing notice for futility) rather than Oregon Revised Statute § 75.490 (which was repealed in 1961).

Finally, to the extent that Plaintiff asserts commencement of this action constituted notice under § 72.6070, the Court notes this argument has been rejected by several courts. For 26 - OPINION AND ORDER

example, in McKay v. Novartis Pharmaceutical Corporation the court granted the defendant's motion for summary judgment on the plaintiff's warranty claims:

Under Texas law, a buyer is required to notify the seller "within a reasonable time" that a breach of warranty has occurred.

* * *

Plaintiffs . . . argue notice was provided by the filing of a class action against Novartis in which McKay would be a member.

* * *

Plaintiffs also contend the nature of bisphosphonate drugs is such that "there was no way for Mr. McKay to know he would suffer BRONJ until he suffered it, and accordingly there was no way for Novartis to 'cure' the problem by additional pre-suit notice." This argument ignores the policies behind the notice requirement: "to enable the seller to make adjustments or replacements or suggest opportunities for cure to the end of minimizing the buyer's loss and reducing the seller's own liability to the buyer; to afford the seller an opportunity to arm himself for negotiation and litigation; and . . . to give the defendant seller the same kind of mind balm he gets from the statute of limitations." By failing to provide Novartis notice about defects in its drugs, it was not provided an opportunity to cure (i.e. by negotiation and settlement) and thereby perhaps obviate the need for this lawsuit.

McKay v. Novartis Pharm. Corp., 934 F. Supp. 2d 898, 912-14 (W.D. Tex. 2013).

The Court concludes Oregon's notice requirement in § 72.6070 is not waived on the ground of futility based on (1) McKay,

(2) the absence of any Oregon law that supports Plaintiff's

27 - OPINION AND ORDER

argument, and (3) the record in this case. Accordingly, the Court grants Defendant's Motion for Summary Judgment as to Plaintiff's claims for breach of express and implied warranties.

<u>DEFENDANT'S MOTION (#45) TO EXCLUDE THE TESTIMONY</u> <u>OF PLAINTIFF'S EXPERT DR. ERIC SUNG</u>

Defendant also moves to exclude testimony by Plaintiff's expert, Eric Sung, D.D.S., on the ground that his testimony does not meet admissibility standards under Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 589 (1993), and Federal Rule of Evidence 702. Plaintiff offers Dr. Sung's opinion and testimony to establish that Aredia and/or Zometa caused Plaintiff's ONJ. Because the Court has concluded Plaintiff has not established a jury question as to any causal connection between Defendant's allegedly inadequate warning and Plaintiff's injury, the Court denies as moot Defendant's Motion to Exclude.

CONCLUSION

For these reasons, the Court **GRANTS** Defendant's Motion (#51) for Summary Judgment, **DENIES as moot** Defendant's Motion (#45) to Exclude the Testimony of Plaintiff's Expert Dr. Eric Sung, **DENIES** as moot all other pending Motions(#47, #49, #53, #55, #97), and

DISMISSES this matter with prejudice.

IT IS SO ORDERED.

DATED this 20th day of March, 2014.

/s/ Anna J. Brown

ANNA J. BROWN United States District Judge